



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR - 3 2007

1155 7 2016 213

Ms. Miledy Santana
President
M. Santana LLC
675 Ogden Avenue
Teaneck, New Jersey 07666

Dear Ms. Santana:

This is in response to your letter of March 9, 2007 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your notice states that M. Santana, LLC is making the claim "[S]upports healthy cholesterol and cardiovascular system."

In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. Because the claim you are making for this product represents that the product is intended to affect blood cholesterol but does not also include a statement about it being intended to affect blood cholesterol that is already in the normal range, it is an implied disease claim.

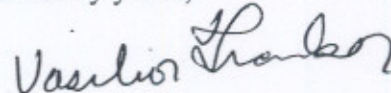
21 U.S.C. 343®(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate disease. This claim does not meet the requirements of 21 U.S.C. 343®(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, Montrose Metro II, 11919 Rockville Pike, Rockville, Maryland 20855.

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Please contact us if we may be of further assistance.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Vasilios Frankos", written in a cursive style.

Vasilios H. Frankos, Ph.D.
Director
Division of Dietary Supplement Programs
Office of Nutrition, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-310

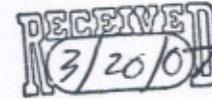
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, New Jersey District Office, Office of Compliance, HFR-CE340

M. Santana, LLC

675 Ogden Avenue
Teaneck, New Jersey 07666

March 9, 2007



Office of Special Nutritional (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C St., S.W.
Washington, DC 20204

RE: Dietary Supplement Statement of Support Notification

Dear Sir or Madam:

M. Santana, LLC, 675 Ogden Avenue, Teaneck, New Jersey, 07666, who is the distributor of the following supplement product, intends to make the following statement of support:

"Cholestromin supports healthy cholesterol and cardiovascular system. This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

This claim is being made for Cholestromin Herbal Supplement.

This submission is being made in compliance with 21 CFR § 101.93.

The undersigned is an authorized representative of M. Santana, LLC and certifies that the information contained in this notice is complete and accurate, and that M. Santana, LLC has substantiation that the above statement is truthful and not misleading.

Sincerely,

A handwritten signature in cursive script that reads "Miledy Santana".

Miledy Santana,
President

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